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AF/1641

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mustapha Abdelouahed and John W. Lawler		
Application No.:	10/084,832	Group:	1641
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Confirmation No.:	5718		

For: DIAGNOSTIC ASSAY FOR TYPE 2 HEPARIN-INDUCED THROMBOCYTOPENIA

CERTIFICATE OF MAILING OR TRANSMISSION

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INTERVIEW SUMMARY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

A telephonic interview was conducted on March 30, 2004. Participants were:

Examiner Deborah A. Davis

Supervisory Examiner Long V. Le

Attorney Carol A. Egner

The Examiners are thanked for holding the interview.

No new exhibits or new Declarations were presented. Examiner Davis was sent by fax an informal paper, not to be entered, "Points to Consider for Interview," preceding the interview.

US Patent No. 5,466,582 by Amiral was discussed. It is relevant to all the claims currently under examination.

Points Presented During Interview

The complexes made by Amiral (US 5,466,582) were of two components only: platelet factor 4 and heparin. The platelet factor 4 used in Example 2 of US 5,466,582 was purified as in Example 1 and does not contain thrombospondin-1. Thrombospondin-1 was separated from platelet factor 4 in Example 1. See column 9, lines 47-50 and line 55. Claim 1 requires heparin, platelet factor 4 and thrombospondin-1 to be in one complex.

A "complex" in biology, as it is understood by one of ordinary skill in the art, refers to molecules bound together by non-covalent bonds. A heparin-agarose column (see Example 1 of US 5,466,582) can be used to separate a mixture of molecules on the basis of non-covalent interactions (for example, ionic bonds) between heparin and (for example, in this case) platelet components. The ionic bonds between heparin, and, for example, platelet factor 4, are interrupted by the salt in a buffer with a gradient of increasing salt concentration. Heparin-agarose is a chemical conjugate produced by a chemical conjugation process that results in covalent bonds between the heparin and the agarose. This is different from a complex as spoken of in biology.

It is known that heparin can bind to platelet factor 4. It is also known that heparin can bind to thrombospondin-1. Heparin-agarose and heparin-Sepharose have been used as chromatography materials for affinity chromatography to purify platelet factor 4. However, there is no evidence that platelet factor 4 and thrombospondin-1 can both bind to heparin at the same time to form a ternary complex of heparin, platelet factor 4 and thrombospondin-1, which is what is required for claim 1.

In a heparin-agarose column or a heparin-Sepharose column, there is no free heparin. There can be no complexes of heparin and platelet factor 4 and thrombospondin-1. It is possible that heparin-agarose may bind platelet factor 4 and thrombospondin-1 at the same time, although there is no evidence of it, and it cannot be assumed. Even if heparin-agarose were to bind platelet factor 4 and thrombospondin-1 at the same time, this is not an isolated complex comprising heparin, platelet factor 4 and thrombospondin-1. Heparin-agarose bound to platelet

factor 4 and thrombospondin-1 would not be isolated. This would only exist in a chromatography column. It would not be a complex of heparin, platelet factor 4 and thrombospondin-1. It would be a complex of heparin-agarose, platelet factor 4 and thrombospondin-1. Heparin-agarose is a chemical entity different from heparin.

Respectfully submitted,

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